PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PC25968A	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/IB2005/000711	International filing date *(day/month/year)* 18.03.2005	Priority date *(day/month/year)* 30.03.2004
International Patent Classification (IPC) or national classification and IPC G01N33/15, B01L3/00		
Applicant PFIZER PRODUCTS INC. et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *sent to the applicant and to the International Bureau)* a total of sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☒	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
12.05.2005	21.02.2006
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Johnson, K Telephone No. +49 89 2399-

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IB2005/000711

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-42	as originally filed

Claims, Numbers

1-15	as originally filed

Drawings, Sheets

1/6-6/6	as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IB2005/000711

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	4 7 10 11
	No:	Claims	1-3 5 6 8 9 12-15
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-15
Industrial applicability (IA)	Yes:	Claims	1-15
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

Section V. Reasoned statement under Rule 43bis.1(a)(i) PCT

1. The following documents are referred to in this communication:

D1 = EUROPEAN JOURNAL OF MEDICINAL CHEMISTRY, vol. 37, no. 5, May 2002, pages 399-407, XP004372956 ISSN: 0223-5234;
ZHU C ET AL: "A comparative study of artificial membrane permeability assay for high throughput profiling of drug absorption potential"
(cited in description)

D2 = INTERNATIONAL JOURNAL OF PHARMACEUTICS, vol. 39, no. 1-2, 1987, pages 59-74, XP002330920 ISSN: 0378-5173;
LEE S J ET AL: "Ion-paired drug diffusion through polymer membranes"

2. Document **D1** discloses a method for evaluating a pharmaceutical composition comprising a drug (cf. D1, page 400, left-hand column, paragraph 2 'The primary goal...' - page 401, right-hand column, paragraph 1 '... to 2h)'. The method comprises:

- providing a microporous membrane having a plurality of pores, said membrane having a feed side and a permeate side; wherein said feed side of said membrane is in fluid communication with a feed solution, and wherein said permeate side of said membrane is in fluid communication with a permeate solution;
- administering said pharmaceutical composition to an aqueous solution to form said feed solution; and
- measuring the concentration of said drug in said permeate solution.

Furthermore, **D1** explicitly advocates the use of a hydrophilic membrane, whereby '... said feed side of said membrane is hydrophilic'.

Therefore the subject matter of claim 1 is not new over this prior art, in contravention of **Article 33(2) PCT**.

2.1 As a similar argument can be derived from document **D2**, it takes away the novelty

of claim 1 as well (cf. D2, page 66 - page 72 'Permeation studies through polymer membranes'). Moreover, it teaches the use of non-aqueous media, especially propylene glycol, for the permeate solution. So independent claim 2 also lacks novelty over **D2**.

2.2 Dependent claims 3-13 do not appear to provide a basis for new and inventive subject matter either. This is because the additional features introduced by these claims are already known from the prior art (claims 3, 5, 6, 8, 9, 12, 13) else represent obvious alternatives to the measures adapted there (claim 4, 7, 10, 11). In particular, since the hydrophilic membrane in **D1** is impregnated on the receptor side with lecithin in dodecane solution, it must be hydrophobic on the receptor side. Whence it satisfies at least implicitly the conditions set on the contact angles by claim 6. Thus adopting these measures either singly or in combination would not betoken inventive skill.

3. Turning now to the independent apparatus claims, claims 14 and 15, both **D1** and **D2** disclose an apparatus with all the features of claim 14, and **D1** explicitly teaches a multi-well plate device according to claim 15. Therefore this subject matter must fall for lack of novelty also.

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